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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,846	09/23/2003	Graham Smith	GP30201V	4957

7590 02/07/2008  
GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939

EXAMINER
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LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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02/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/668,846	<b>Applicant(s)</b> SMITH ET AL.	
	<b>Examiner</b> JON M. LOCKARD	<b>Art Unit</b> 1647	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 04 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: \_\_\_\_\_.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

/Christine J Saoud/  
 Primary Examiner, Art Unit 1647

Continuation of 11. does NOT place the application in condition for allowance because: Claims 3-4 remain rejected under 35 U.S.C. § 101 and 112(1) (Enablement). The basis for this rejection is set forth at pg 2-10 of the previous Office action (mailed 05 September 2007) and at pg 4-9 of the Office action mailed 23 February 2007. No substantially new arguments have been presented, and thus the rejection is maintained for reasons of record. The instant application does not disclose a specific biological role for the claimed VANILREP4 protein or the nucleic acid that encodes it, or its significance to a particular disease, disorder, or physiological process which one would manipulate for a desired physiological or clinical effect. Moreover, while the specification discloses that both PMA and 4αPDD activate the hVR4 receptor in HEK293 cells expressing recombinant hVR4, the specification as filed fails to disclose the physiological consequence of that activation or any beneficial effect from said activation, and there is no evidence of record that this in vitro activity is predictive of any particular in vivo activity. Furthermore, whereas one could readily employ the putative VANILREP4 protein of the instant invention in an assay to identify modulators thereof, the information obtained from such assays would be of little use until one discovers the identity of those physiological processes mediated by that putative VANILREP4 protein. Because the instant specification has failed to identify a physiological process which has been shown to be influenced by the activation or inhibition of the putative VANILREP4 protein of the instant invention, an artisan would have no way of predicting what effects the administration of that modulator to an organism would have. If one cannot predict the effects that the administration of a modulator of the VANILREP4 protein of the instant invention is going to have on an organism, then it is unclear as to what practical or real world benefit is derived by the public from the identification of that modulator. In summary, the specification fails to establish a nexus between the observed hVR4 activity in a recombinant cell line and a physiologically relevant process which one would wish to manipulate (i.e., via administration of an agonist or antagonist) to achieve a beneficial effect in an individual.